**REMARKS**

Prior to this Response, claims 11, 14-15, and 27-35 were pending in this application. Claims 30 and 35 have been amended.

The amendments, including the previously added new claims 27-35, do not introduce new matter within the meaning of 35 U.S.C. §132 as discussed in detail below. Accordingly, entry of the amendments is respectfully requested.

**1. Clarification regarding the Specification**

The Office Action requests clarification for the following reasons:

> There appears to be text missing and/or a document editing error on pages 61-62 of the specification. The bottom of page 61 is blank and the top of page 62 is blank.

Applicants thank the Examiner for her concern regarding pages 61-62 of the specification. The application as filed contains text running through the end of line 33 of page 61, and from the beginning of line 1 of page 62, which appears to form the following complete sentence: "In accordance with the preceding explanation it should now be understood that the present invention embodies new, neural-network-based, methods of identifying and relating particular alleles--out of a vast number of alleles present in the genomic sequences of each of a large number of individual organisms--that are relevant in a practical sense to (i) some

particular biological or sociological problem, normally disease, afflicting or besetting the organisms, and, separately, to (ii) various therapies, normally drugs but also including environmental changes, that may be applied to the organisms in mitigation or alleviation of the problem." No text is missing. Thus, it is unclear to Applicants exactly what the Examiner refers to in this rejection. Applicants and their counsel will be pleased to discuss this matter further, should the Examiner deem it necessary following this Response.

Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw, or further explain, the request for clarification regarding the Specification.

**2. Rejection of Claims 30-35 under 35 U.S.C. §101**

The Office Action rejects claims 30-35 under 35 U.S.C. §101 for the following reasons:

> "[T]he claimed invention is directed to non-statutory subject matter. Claims 30-35 are directed to a neural network per se.
>
> As written, the claims contain no structural or functional interrelationship with a computer-readable medium that would allow the function of the descriptive material to be realized."

Applicants thank the Examiner for her helpful comments regarding statutory subject matter. Applicants have amended claims 30 and 35 to indicate that, as is known to one of ordinary skill in

the art, a neural network resides on a computer, in order to overcome this rejection. Basis for these specific amendments is found particularly at page 25, lines 9-14; page 38, lines 24-27; and elsewhere in the application.

Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the rejection under 35 U.S.C. §101.

## 3. Rejections under 35 U.S.C. §112, first paragraph

### A. Written Description/New Matter

The Office Action rejects claims 27-35 under 35 U.S.C. §112, first paragraph, for the following reasons:

> "Claims 27-35 are not originally filed claims. Claims 27-28 depend upon claim 11 and claims 29, 30, and 35 are independent claims. Applicant has not pointed to basis in the specification for these claims and none is apparent."

Applicants thank the Examiner for pointing out that the basis in the Specification for new claims 27-35 was not stated in the application as filed. However, contrary to the Office Action, there is basis in the Specification as filed for the new claims. Claims 27 and 28 relate to the necessity of obtaining patient samples containing one or more of the listed datums prior to training of the neural network. Section 1.1 of the Specification, 'Our Connection with the Patients,' describes these inputs. Applicants are not claiming a method to obtain such samples; but

rather of analyzing them. For the collection of data, one skilled in the art is a medical professional, all of whom are trained and have for centuries routinely performed such collection activities as a matter-of-fact. Also see Section 2.2 of the Specification, 'Teaching of the Present Invention - One' at page 41, line 10: "We first obtain a set of examples of clinical inputs and their corresponding outputs". As mentioned numerous times in the text of the application, these inputs and corresponding outputs are what are referred in claims 27 and 28.

Claims 29-35 are related, essentially, to predicting drug efficacy. This is specifically taught in section 1, at page 28, line 10; in section 1.4, at page 34; in section 1.5, at page 35; in section 1.6, at page 37, line 4; in section 3.3, at page 45; in section 5.4, at page 55; in section 6.3, at page 58; in section 6.4, at page 60; and in section 6.5, at page 61.

Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw this rejection.

**B. Enablement**

The Office Action rejects claims 11, 14-15, and 27-35 under 35 U.S.C. §112, first paragraph, as lacking enablement, for the following reasons:

> "Claim 11 is directed to a method of identifying from the genomic data of an individual organism a suitable therapy for at least one disease of the organism. The method steps include 1) constructing a

neural network to map (i) genomic data in the form of two or more alleles and/or SNP patterns to (ii) historical incidences of responses to therapies for the diseases of a multiplicity of individual organisms, 2) training the neural network, and 3) exercising the trained constructed neural network.

The specification does not provide the information required by either (i) or (ii) nor does it reference any sources of such information. The specification does not provide any working examples of the method. It is believed that the information required to practice the invention would not have been available and did not exist at the time of the invention. The specification fails to provide guidance as to how to obtain the information required by the claimed method. As such, one would not be able to practice the claimed invention without undue experimentation.

* * *

With respect to claims 15 and 32, one of ordinary skill in the art would not know how to define a family. What is a similar expression pattern of a characteristic SNP pattern? What is a characteristic SNP pattern? Do the families include alleles or SNP patterns turned on and off by any gene or the same gene? The specification fails to identify any such families. The specification fails to provide guidance as to what defines these and in the absence of any definition, one of ordinary skill in the art would be unable to practice the invention.

With respect to claims 27 and 33, what defines a gene family? What defines a diet type and home region? The specification fails to provide guidance as to what defines these and in the absence of such a definition, one of ordinary skill in the art would be unable to practice the invention.

The true intent of the claims is a data mining method within a data mining method. That is, to first associate genetic variation to disease and then to associate a particular genetic variation to a form of treatment for that disease. This is an invitation to experiment. While the specification and claims set forth a general research plan for a problem that would have

been known to be of interest (and complex) to those of ordinary skill in the art, the specification has not provided a solution nor sufficient guidance to enable one to find a solution. Again, the specification has not exemplified any method for identification within the claims nor provided guidance on the how to adapt the known statistical techniques for solving the problem at hand. One of ordinary skill in the art would be required to make independent decisions and judgments on how to apply the statistical techniques, what parameters to use or change, assumptions to make, and so forth. Any model developed must be tested and validated. This is not considered to be routine experimentation. It requires one of ordinary skill in the art practicing the invention to use inventive skill to develop applicant's claimed method. Anders et al. is cited to establish the level of skill in the art at the time of the invention with respect to neural networks. Among other things, Anders et al. establishes that for many applications theory does not suggest the relevant input variable or the correct functional form to produce an appropriate model to solve the problem at hand. (See introduction.) Recitation of "constructing a neural network suitable to map" genomic data to therapies for disease is not a routine or straightforward task. It constitutes undue experimentation."

Applicants respectfully traverse this rejection on the basis that a *prima facie* case of nonenablement has not been established. A patent application is presumptively enabled when filed. "As a matter of Patent Office practice...a specification...must be taken as in compliance with the enablement requirement of the first paragraph of §112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." In re Marzocchi, 439 F.2d 220, 223, 169 U.S.P.Q. 367, 369 (CCPA 1971). As pointed out by the PTO in the *35 U.S.C. §112 First Paragraph Enablement Training Manual* (citing *In*

*re Wright*, 999 F.2d 1557, 1561-62, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993), "the case law makes clear that properly reasoned and supported statements explaining any failure to comply with section 112 are a requirement to support a [nonenablement] rejection."

Applicants respectfully submit that a *prima facie* case of nonenablement has not been established because the Office Action fails to advance any such "reasoned or supported statements". In particular, Applicants note that the several examples cited by the Examiner in support of the non-enablement argument teach nothing about the novel use of a neural network in combination with either (a) householding or (b) genetic algorithm rolling.

As the Examiner admits, Layton, et al. investigated whether the therapeutic response of rheumatoid arthritis patients to D penicillamine is associated with polymorphisms in genes of the glutathione-S-transferase (GST) supergene family. No mention of using a neural network in combination with householding or genetic algorithm rolling is made.

Fullerton, et al. investigated apolipoprotein E variation in populations and the association with cardiovascular disease and Alzheimer's disease risk. As the examiner admits, there is no indication in Fullerton, et al. that the optimal response of different drugs for these conditions were known or had been determined, nor that they hade been associated with a particular

disease or allele/SNP. Clearly, the need for the inventive subject matter is shown, and Applicants provide a method to do exactly this, to both *find* the most relevant alleles/SNPs/proteins, etc. out of an initial pool (see claims 15 and 32) and *associate* those with disease response (see claims 11, 14, 27-31, 33-35).

The methodology claimed by the applicant is most certainly ***not*** the haplotyping technique of Judson et al. as this is just a technique of linear correlating clustered alleles on a single locus to disease phenotypes, with no regard to any nonlinear correlations that would reduce the number of alleles under study among other problems. The fact that the authors require massive amounts of haplotypes further shows the need for the instant invention.

The examples by the Examiner cited are however excellent evidence demonstrating secondary factors in support of patentability, including failure of others to recognize the point of novelty and Applicants' fulfillment of a need long-felt in the art.

Even if a *prima facie* case has been established, it would be rebuttable because the assertion by the Examiner that the data required to perform the inventive methods, using the inventive neural networks, is unavailable, is both unsupported and factually inaccurate. In particular, if the Examiner is relying not on published information about neural networks and genomic/SNP data,

but on information known to her personally, then it is respectfully requested that such information be provided in an appropriate affidavit.

Data Availability. The "raw material" for Applicants' methods is human genetic information, along with physiological data, which has been collected in some form essentially since humans have existed. To obtain genetic information from a person, one does not need blood; if one chose, one could just follow around people with, for example, a propensity for a certain drug side effect, and collect shed cells that their body gives off. The techniques involved in isolating DNA have been automated since the late 1980s and the level of knowledge required is at this time little more than a high school education. Medical chart data is obtained in an interview or from existing records.

While biobanks that contain patient information sprang up in the late 1990s, there have been several sample repositories (i.e. blood sample and patient information) through the National Institutes of Health and private institutes such as the HUGO Mutation Database Initiative working group (now known as the Human Genome Variation Society) that were in existence before this application was filed. To obtain such information, one usually goes through a peer-review process, and a person skilled in the art and able to execute the claimed subject matter taught in this

application would have been able to obtain data from private and restricted databases.

Further, there were numerous private researchers at universities or institutes who maintained the necessary information to execute the claimed subject matter, and the only significant barrier to obtaining existing data was, and continues to be, money. One such example is John Kelsoe, professor of medicine at the University of California, San Diego, who since 1989 has maintained a blood sample databank with associated patient information on lithium in bipolar patients, with the adverse effect of the drug being obesity. Again, the information existed in many data repositories, requiring only the resources of time and money, and perhaps the need to convince an Institutional Review Board that one's application is a sufficiently worthwhile effort to be associated with.

Applicants' have submitted a Hypertension Response Prediction Final Report to NSF to show that patient genotype-phenotype information was available, and that the instant invention actually works exactly as predicted in the present application. Applicants licensed the specific information used in this work from Pharsight, Inc. in January of 2001. However, Pharsight in turn licensed the data from Duke University in 1999, and thus the relevant data was available at the time of this application filed.

Patient studies have also been done for decades and are designed by people trained to run them. The information obtained in most studies includes: drug(s) taken, which is necessarily and obviously maintained as a matter of record; drug dosages and/or efficacy data, as maintained in patient chart medical records, and which are part of any drug study; adverse event(s) notes, also found in patient medical records; genomic data, which is gained as a tissue or blood sample and then genotyped by techniques that have now been around for at least two decades. Applicants maintain that a person with ordinary skill in the art could have designed and run a study specifically to collect data for the instant invention. To back up this claim, Applicants have submitted an affidavit from Dr. Nicholas Schork in the parent application, which clearly refutes the Examiners' assertions relating to the purported non-existence of genomic/SNP data.

In particular, as to the availability of markers, Applicants respectfully remind the Examiner that a "working draft" of the human genome was completed on June 26, 2000 and therefore essentially all SNP markers of interest (i.e. in genomic coding regions), patterns of which were referenced in the instant Specification, were technically known at the time this application was filed.

The Office Action further states that one practicing the

instant invention would not have access to further mine patient response data. This assertion is unsupported in the record and is factually incorrect. It is the policy of the U.S. government that all publicly funded studies (for example, through NIH) publish their information, including patient information as long as specific patients have had any identifying information (i.e. name, record number, location, etc.) removed. One can also get the information through the Freedom of Information Act.

Applicants additionally provide the example of Golub et al. (1999) to show that this information was available in widely-published papers before this patent application was submitted. Indeed, the reason this application was submitted is because many people talked about the availability of such data, but Applicants were the first to address a method of comprehensive analysis of such data to predict a clinical outcome!

The Office Action further states that one of ordinary skill in the art would not know how to define a family of genes and/or SNPs. The Examiner has shown this is not true by the cited example of Layton, et al., which discusses precisely what gene families are. Researchers have had to know how to do candidate gene studies since the examination of metabolic genes and their effects began in the 1950s. To put together gene fammily listings is common knowledge and not novel to one of ordinary skill in the art, as referenced

above in relation to the HUGO database (available since 1996).

Similarly, it is known in the art that a similar expression pattern of a characteristic SNP pattern is a group of SNPs that are genetically identical in the response phenotype they generate, i.e. in linkage disequilibrium with each other. A characteristic SNP pattern is a group of SNPs that are associated with a specific phenotype. See, for example, page 43, line 1 of Specification herein. Read in conjunction with the Specification, and using definitions known in the art, claim 15 is understood as follows:

> "grouping alleles and/or characteristic SNP patterns into families as are defined by (i) having similar expression patterns <<defined as in linkage disequilibrium with each other>> or being turned on and off by another gene <<defined as being in the same biochemical pathway>>, or (iii) both having similar expression patterns and being turned on and off by the same gene <<defined as being in linkage disequilibrium and being in the same biochemical pathway>>". . .

This wording is instantly recognizable to most people familiar with the basics of genetics and molecular biology, and certainly recognizable to those practiced in the ordinary skill in the art in these fields. Applicants do not identify lists of gene families, since such would be useless unless one was claiming relation to a specific disease, which Applicants are not.

Similarly, diet type simply refers to the diet a person is on, which is expected to change according to the culture and/or religious regions. Home region is simply where someone lives.

Applicants respectfully submit that these terms are extraordinary obvious to one of ordinary skill in the relevant art. Applicants do not understand the basis for a rejection relating to definitions of such straightforward terms.

Finally, the examiner asserts that the instant invention leaves too much to experimentation, stating: "[H]ow to apply the statistical techniques, what parameters to use or change, assumptions to make, and so forth. Any model developed must be tested and validated. This is not considered to be routine experimentation."

First, it must be pointed out that the instant invention is not a statistical technique. It is a machine-learning technique, i.e. a computer algorithm, using both a neural network with inputs as described and or arranged in the instant invention alone or in combination with a genetic algorithm in the manner as described by the instant invention. A relevant distinction is that mere statistical techniques need a mathematical function related to a known a prior distribution. The instant invention does not. This is well-known to one of ordinary skill in the art.

Applicants offer the following relevant history, as relates to an understanding of the inventive subject matter. In 1959, Bernard Widrow and Marcian Hoff of Stanford University developed the first neural network models, models they called ADALINE and MADALINE.

These models were named for their use of (Multiple) ADAptive LINear Elements. MADALINE was the first neural network to be applied to a real world problem. It is an adaptive filter which eliminates echoes on phone lines. This neural network is still in commercial use.

By 1985, the American Institute of Physics began what has become an annual meeting - Neural Networks for Computing. By 1987, the Institute of Electrical and Electronic Engineer's (IEEE) first International Conference on Neural Networks drew more than 1,800 attendees. By July 2000, over 5,000 papers were referenced in INSPEC with terms relating to neural networks.

Thus, it is well established that there was, at the time of filing of the instant application, a large community of people with working knowledge on how to construct an ordinary neural network. Simple black box neural networks were publicly available at this time; for instance, see neural network toolbox 1.0, from The Mathworks (http://www.mathworks.com/products/neuralnet/; http://diwww.epfl.ch/mantra/tutorial/english/weblinks.html for date verification). Applicants enhanced the off-the-shelf neural network by using a genetic algorithm in a manner taught in the present application, and apply such combined algorithm to a novel use, that of detection, diagnosis, and finding suitable treatment of human disease.

Second, the parameters of the neural network (such as the number of inputs, or the number of nodes) are automatically adjusted by the genetic algorithm (see, for example, page 15, lines 11-19 for an overview of the method to adjust the number of nodes and inputs described further in the patent application) or by hand (see for instance page 14, line 31 to page 15, line 10 for an overview of the method to adjust the number of inputs described further in the patent application). Thus, with Applicants' method, no manual adjustment is necessary. This is demonstrated in working examples in studies relating to hypertension and the use of citalopram in treating depression.

Third, Applicants respectfully disagree with the Examiner's conclusion that construction of a mapping neural network is not a routine task to one of ordinary skill in the art. The examiner asserts that Anders, et al. "establishes that for many applications theory does not suggest the relevant input variable or the correct functional form to produce an appropriate model to solve the problem at hand." As to the former, the instant invention teaches a method to determine the relevant input variable(s) as discussed previously, and a correct functional form (assuming that the examiner means a method by the term "functional form", and the neural network architecture by "appropriate model"). As to the latter, the neural network model is optimized (i.e. made

"appropriate") by the method of using a genetic algorithm according to sections 2.2, 3.3, 4.2, 5.2, and 6.2 of the application as filed. Applicants agree that mapping medical variables to therapies for disease is not a routine task, hence the need for the instant invention. It is the neural network set-up that is routine. Applicants respectfully refer the Examiner to the Figures, particularly the flowcharts in Figures 1c and 1d, as well.

In Northern Telecom, Inc. v. Datapoint Corp., 908 F.2d 931, 942 (Fed. Cir. 1990), the Federal Circuit articulated a relaxed standard of enablement that applies to software patents: "The computer language is not a conjuration of some black art, it is simply a highly structured language.... [T]he conversion of a complete thought (as expressed in English and mathematics, i.e. the known input, the desired output, the mathematical expressions needed and the methods of using those expressions) into a language a machine understands is necessarily a mere clerical function to a skillful programmer."

The inventive subject matter here is essentially a computer program, albeit a sophisticated program, combining two known elements into a neural network having novel properties and able to resolve problems previously beyond resolution. As is quite clear from CCPA and Federal Circuit case law, not everything necessary to practice the invention need be disclosed. In fact, what is

well-known is best omitted. In re Buchner, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991). Applicants have disclosed the necessary details of the neural network at the level of program function, and are not required to disclose of the actual source code implementation. The inventive subject matter is thus fully enabled.

Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw this rejection.

**4. Rejection of Claims 11, 14-15, and 27-35 under 35 U.S.C. §112, second paragraph**

The Office Action rejects claims 11, 14-15, and 27-35 under 35 U.S.C. § 112, second paragraph, for the following reasons:

> Claim 11 is confusing in that the lengthy preamble does not correspond to the body of the claims. For example, the preamble recites that the goal is to "determine which of a large number of alleles... are ... relevant ... individually and in combination, to certain biological and social variables..." However, the body of the claim does not require large numbers of alleles nor biological nor social variables. In fact, the body of the claims recites "two or more alleles and/or SNP patterns." Thus, in some embodiments the claimed method is not required to evaluate alleles at all. Applicant is requested to identify clearly those elements set forth in the preamble that the method steps in the body of the claim are supposed to accomplish.
>
> Claim 11 also requires "numerous." It is not known how many examples would meet this limitation. See also at least claims 27, 29, and 35.
>
> Claim 15 requires grouping into families having "similar" expression patterns. It is not known what level of

similarity would meet this limitation.

Claim 27 recites "a first group consisting essentially of entire, gene families, specific alleles, ..." The recitation of "consisting essentially of' is confusing as it does not make clear what is included or excluded. That is, what particular property or characteristic is "essential" to members of the group? See also the second group recited in claim 27 as well as claims 28, 33, and 34.

Claim 35 recites "sot trained." This appears to be a typographical error.

Applicants thank the Examiner for her helpful comments relating to possible indefiniteness in certain of the claims. Applicants have amended claims 30 and 35, and the foregoing claim amendments obviate the rejection relating to the typographical error in claim 35.

Applicants respectfully traverse the remaining rejections under U.S.C. 112, second paragraph. The terms cited by the Examiner as being indefinite are either well known in the art, defined in the Specification, or both.

The inventive subject matter essentially relates to a methodology for computationally predicting an outcome of clinical interest. This methodology is to apply to all disease, and the (presumed) assertion by the examiner that the particular disease has to be pointed out is actually irrelevant to the inventive subject matter, which is not so limited.

Claim 11 refers to "a large number of alleles," while the

technique involves using a neural network "suitable to map (i) genomic data in the form of two or more alleles." What defines a large number of inputs, or alleles in this case, for neural networks is the number of training examples. If one only has ten or less examples to train on, then two inputs is a large number. The rule of thumb, well-known by one of ordinary skill in the art, is that the number of inputs for a three-layer--input, hidden, and output layer--neural network is one-tenth of the number of total network weights. This also applies to the word "numerous," this time relating to the number of training examples. Applicants respectfully request a consultation with the Examiner on this subject, if this response is unclear or further discussion is deemed to be useful to advance prosecution.

The definition of "similar expression patterns" is taught by Applicants on page 14, line 31 to page 15, line 10: "The present invention still further contemplates two new methods of training a neural network. The first method, applicable to genomic data, is called "householding". This method limits the amount of relevant genes by considering (as inputs to the neural network model) only those genes whose expression is similar. In other words, genes are grouped into families based upon whether they are "on" or "off" at the same time (if this information is known *a priori*). If two or more genes are on or off at the same time, then there is a high

probability that they are related, or both are controlled by a third gene. This statistical technique is called "householding", the "householded" genes being treated as a single input to the neural network. This process reduces the amount of data that has to be gathered for use, and the required size of the neural network (which size is related to solution complexity, and time)."

Thus, it is clear that the level of similarity is binary, i.e. either on together or off together, this being particular to an individual gene chip, but since the genes are expressed together on the same chip, thresholds do not matter to the level of error of the particular chip. This is well-known to one of ordinary skill in the art. See for example Chenchik et al. 1998, 'Profiling of Gene Expression in a Human Glioblastoma Cell Line Using the Atlas(tm) Human cDNA Expression Array I'.

The property that is essential to members of the group is that they are similar in biochemical function and/or have been found to be expressed in a similar fashion in a normal or disease process. The general function of inclusion or exclusion is determined by the instant invention, as described in sections 2.2, 3.2, 4.2, 5.2, and 6.2 with applications in the following sections.

Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw this rejection.

**5. Rejection of Claims 11, 14, 27-28, 30-31, 33-35 under 35 U.S.C. §102(e)**

The Office Action rejects claims 11, 14, 27-28, 30-31, 33-35 under 35 U.S.C. §102(e) as being anticipated by Roberts (US 2003/0198970 A1; hereinafter, the '970 application). As the basis for this rejection, the Office Action states the following:

> "Applicant claims priority to 09/611,220 filed 7/6/00 as well as 09/451,249 filed 11/29/99. Applicant is not entitled to benefit of the 09/451,249 filing date as this application does not disclose the invention presently claimed. For example, this parent application does not disclose nor contemplate genomic data, alleles, or SNP patterns. As such, the instant application's effective filing date is 7/6/00.
>
> Roberts teaches using a genetic algorithm to associate genomic and pharmacological profiles to individually tailor therapeutic packages. Lists of core genes are disclosed. See at least abstract, claims, Examples 6-7, paragraphs [0013-0017], [0044-0046], and [0136-0140]. Implicit in the disclosure that a genetic algorithm is used is that the neural network must be trained such that it is fit, possesses a measure of goodness, and that it is used to identify the particular therapy and genomic data. The specific allele, race, ethnicity, and pharmacological information required by claims 27-28 would be routinely collected from the population and form part of a clinical analysis."

Applicants respectfully traverse this rejection. The cited reference was published on October 23, 2003, ***more than three years after*** the effective filing date of the present application conceded by the Examiner, and thus is not an effective reference under 35 U.S.C. §102(e)(1). Further, the '970 publication has not matured into a patent, and may never mature into a patent, and thus is not

a proper reference under 35 U.S.C. §102(e)(2).

While it is to be noted for the record that Applicants absolutely do not concede the correctness of the Examiner's conclusion that the effective filing date of the present application is July 6, 2000, the point is moot for the present discussion; under any interpretation of the filing dates of the parent applications, the '970 publication is not a valid reference.

Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw this rejection.

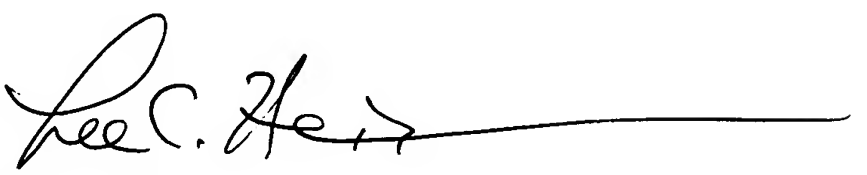
**CONCLUSION**

Based upon the above remarks, the presently claimed subject matter is believed to be novel and patentably distinguishable over the prior art of record. The Examiner is therefore respectfully requested to reconsider and withdraw the rejections of the remaining claims and allow pending claims 11, 14-15, and 27-35 presented herein for reconsideration. Favorable action with an early allowance of the claims pending in this application is earnestly solicited.

The Examiner is welcomed to telephone the undersigned attorney if she has any questions or comments.

Respectfully submitted,

**NATH & ASSOCIATES PLLC**

Date: September 14, 2004 By: 

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